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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,632	07/30/2002	Erik D'Hondt	B45201	7231

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EXAMINER
MOSHER, MARY

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/30/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,632	Applicant(s) D'HONDT ET AL.	
	Examiner Mary E. Mosher, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *26-51* is/are pending in the application.

4a) Of the above claim(s) *37-41,46 and 48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *27-29,32-35,42-45 and 47* is/are rejected.

7)☐ Claim(s) *30 31 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on 30 September 1999. It is noted, however, that applicant has not filed a certified copy of the GB application as required by 35 U.S.C. 119(b). No copy was provided by any International Office. Therefore the effective filing date is 27 September 2000, the filing date of PCT/EP00/09509.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 26-50 have been renumbered 27-51.

In the interest of compact prosecution, it is assumed that applicants intended to cancel original claim 26 in the Preliminary Amendment filed 20 March 2003, and original claim 26 has not been further treated. If this is correct, please cancel claim 26 in the next response.

Election/Restrictions

Claims 37-41, 48-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6. In addition, claim

46 is withdrawn; this claim was erroneously included in group I, but it should have been placed in group II. Therefore claims 27-36, 42-45, and 47 are examined.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 31 has changed the aluminum salt concentration from 0.4-1 milligrams per dose (in original claim 6) to 0.4-1 micrograms per dose. Applicant is requested to point to support for this concentration, as support in the original specification is not apparent to the Examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-29, 33-35, 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Couch et al (Journal of Infectious Diseases 176:S38-S44, 1997), Chaloupka et al (European Journal of Clinical Microbiology & Infectious Disease 15:121-127, 1996), and Kistner et al (WO 00/15251). The English-language equivalent of Kistner et al (US 6,372,223) is also provided for convenience. Couch discusses influenza pandemics, and explicitly suggests developing adjuvants to produce satisfactory immune responses with lower doses of antigen to decrease the burden of vaccine production in a pandemic circumstance. See for example page S41, first paragraph, and page S42, second paragraph. Chaloupka teaches that current human influenza vaccines are required to contain 15 ug hemagglutinin per strain per dose. Therefore Couch suggests a vaccine with less than 15 ug hemagglutinin per dose. Kistner teaches that an egg-derived influenza virus vaccine containing 1.5 ug hemagglutinin per dose, combined with aluminum hydroxide adjuvant, is at least as effective as the 15 ug dose, see table 1, line L. Therefore, it would have been within the ordinary skill of the art to carry out the suggestion of Couch, using egg-derived antigen and aluminum salt adjuvant, with reasonable expectation of success. The invention as a whole is prima facie obvious, absent unexpected results.

Claims 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Couch et al, Chaloupka et al, and Kistner et al as applied to claims 26-28, 32-34, 41-43 above, and further in view of Riberdy et al

(Journal of Virology 73:1453-1459, 1999). These claims differ from the above in that they specify H2 or H5 hemagglutinin. Riberdy teaches that H5N1 virus is thought to have pandemic potential, and that an H5N1 virus is being used to develop a vaccine intended for humans, see page 1453, column 1. Therefore, it would have been obvious to choose an H5N1 virus for use to vaccinate against a potential pandemic strain. The invention as a whole is prima facie obvious, absent unexpected results.

Allowable Subject Matter

Claims 30, 31, and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or particularly suggest a combination aluminum phosphate/aluminum hydroxide adjuvant for a low-dose pandemic strain egg-derived vaccine, or protease digestion of non-influenza proteins in the preparation of the low-dose egg-derived vaccine.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 703-308-2926. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers

for this Group are now (703) 872-9306 for Before Final responses, and (703) 872-9307 for After Final responses. Faxes for this Group can also be sent to (708) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

July 29, 2003

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600 1600